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10/785,093	02/25/2004	Xavier Blin	05725.1263-00	8509	
22852 7590 971102908 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAM	EXAMINER	
			RAE, CHARLESWORTH E		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/785.093 BLIN ET AL. Office Action Summary Examiner Art Unit Charleswort Rae 1611 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 April 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-114 is/are pending in the application. 4a) Of the above claim(s) 1-77.103.104 and 106-113 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 78-102,105 and 114 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date 9/7/05

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

DETAILED ACTION

Applicant's response, received 4/14/08, to the restriction/election requirements, mailed 7/2/07, electing invention I (claims 1-107 and 114) and, anhydrous composition in the form of a lipstick according to Example 2 as the composition species, acetic acid as a carboxylic acid species, sucrose as the alcohol species, the acrylic copolymer from Example 1 as the polymer particle (ie. poly – methyl acrylate/acrylic acid) as the acrylic copolymer species, block polymers as the stabilizer species, polycaprolactones as the gelling agent species, polyethylene wax as the wax species, is acknowledged (see applicant's Response, received 4/14/08, at pages 20-21).

Status of the Claims

Claims 1-114 are currently pending in this application.

Claims 1-77 and 103-104, and 106-113 are withdrawn for being directed to nonelected subject matter.

Claims 78-102, 105, and 114 are presented for examination.

Claim Amendments

Applicant's amendment received 4/14/08 is acknowledged. Applicant's statement that support for the amendment of claim 101 to recite the term "at least one compound chosen from sucrose acetate isobutyrate" may be found throughout the specification and claims as originally filed, for example, Example 2 of the specification and para. 078, 082, and 084, is also acknowledged and made of record.

Restriction/Election

10/785,093 Art Unit: 1614

Applicant's conclusory statement disagreeing with the restriction and election requirements is acknowledged (see applicant's Response, received 4/14/08, at page 19). However, applicant's response to the requirements is considered to be without traverse because applicant has failed to point out any specific error in the restriction/election requirements.

The restriction/election requirements are made final.

Foreign Priority

Receipt of applicant's certified copy of the foreign priority application received 9/19/04 is acknowledged. It is noted that in the absence of a filed certified copy of the English translation of the foreign priority application, the effective filing date for prior art purposes is considered to be March 6, 2003 (= filing date of the provisional application).

REJECTIONS

LACK OF WRITTEN DESCRIPTIN UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 78-102, 105, and 114 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals having a certain solubility parameter, a particular molecular mass, and/or non-ionic polar groups, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However,

10/785,093 Art Unit: 1614

claims 78-102, 105, and 114 are directed to encompass compounds described only as having a particular solubility parameter, and/or a particular molecular mass, and/or a non-ionic polar group, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of the undisclosed compounds described as having a particular solubility parameter or molecular mass, and/or nonionic polar groups, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

<u>Vas-Cath Inc. v. Mahurkar</u>, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not 'clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u> at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed compounds, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("TIPh description must clearly allow persons of ordinary skill in the art to

10/785,093 Art Unit: 1614

recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPO2d at 1966.

Therefore, only the disclosed chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that <u>Vas-Cath</u> makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claim rejections - 35 USC 112 - Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 87-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 87 recites the term "wherein the at least one compound comprises no polar group chosen from ionic or non-ionic polar groups" renders the claimed subject unclear in view of dependent claim 88 which recites "wherein the non-ionic polar groups are chosen from ..." Thus, claims 87 and 88 are found to be indefinite.

Claims 89-95 are also rejected for reciting either the term "where the solubility parameter, ..., of the compound ..." or the term "where the compound is present, ..."

Recitation of either term renders the claimed subject matter indefinite because it is not

10/785,093 Art Unit: 1614

clear what the term "the compound" specifically refers back to with respect to the antecedent claims. Thus, the recitation of the term "the compound" renders the claimed subject matter indefinite for lacking a proper antecedent basis.

Claims 89, 90, 91, and 92 are also rejected under 112, 2nd for lacking proper antecedent basis. Claim 78 recites "wherein the solubility parameter, ..., ... ranges from 5.5 to 11," which fails to provide proper support for the solubility parameters < 5.5. as recited in claims 89-92. Thus, these claims are found to be indefinite.

Claims 97 and 99 are also rejected under 112, 2nd for lacking proper antecedent basis. Claim 97 recites the term "wherein the mass ratio" Claim 95 from which said claim 97 depends do not provide proper antecedent basis for the term "wherein the mass ratio" Thus, claim 97 is found to be indefinite.

Claim 99 is rejected for the same reason for failing to correct the deficiency of the claim from which it depends (i.e. claim 97).

Claim rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 78-92, 93-95, 96-100, 102, 105, and 114 are rejected under 35 USC 102(a) as being anticipated by Ferrari et al. (US Patent Application Pub. No. 2002/0164297 A1).

The limitations with respect to solubility parameters, for example, recited in claims 89 and 91; the limitations with respect to molecular mass, for example, recited in

10/785,093 Art Unit: 1614

claims 83, 84, 85, and 86; and the limitations with respect to mass ratio, for example, recited in claims 96, 98, and 100 are construed to be inherent characteristics of the claimed composition.

Ferrari et al. teach the following (see paras. 0140-0134):

EXAMPLE 1 OF A POLYMER DISPERSION

[0140] A dispersion of polymethyl methacrylate constituted with ethylens glycol dimethacrylate, in hydrogenated polysicotutene (containing 5.5 mol of sicotuylate), soid under the name Patleam by the company Nippon Oil Pat, is prepared according to the method of Example 2 of document EP-A-749 746, replacing the Isopar L with Patleam A dispersion of polymethyl methacrylate particles that are surface-stabilized in the Patleam with a polystyrene/copolycethylane-propyleos) dislock coopsymer, soid under the name Katon Oi 7010 (Shell), having a selidisc content of 22-25% by weight and a Tg of 100° C, is thus obtained. This propyleos of the first path of the propyleos of the foreign at uniform temperature.

The dispersion exemplified by Ferrari et al., which is identical to the polymer dispersion component encompassed by the instant claims, satisfies the embodiment "b" as recited in independent claims 78 and 114. The hydrogenated polyisobutene exemplified by Ferrari et al. reasonably satisfies the liquid fatty phase component of the instant claimed composition i.e. embodiment "a" of independent claims 78 and 114. Ferrari et al. exemplify the following lipstick formulation (para 0140):

Application/Control Number: 10/785,093

Art Unit: 1614

COUNTEREXAMPLE 1

lipstick				
	Phase A			
	Polyothylene was	1346		
	Carasuta wax	2%		
	Discotestvi meiate	695		
	Dispersion of Exemple 2	50%		
	Parleant	3-%		
	Phase B			
	Lanolin	6%		
	Pigments	5.55%		
	Discersant	2%		
	Patienn	9,34%		

The term "at least one compound having a solubility parameter, ..., ..., the at least one compound being present in an amount sufficient to plasticize the at least one polymer particle", for example, as recited in claims 78 and 114, given its broadest reasonable possible interpretation is construed to encompass disostearyl maleate exemplified by Ferrari et al. (as shown above).

Claims 89-92 are also rejected under 102(a) as being anticipated by Chevalier et al. (US Patent 6,361,782).

The limitations with respect to molecular mass, for example, recited in claims 83, 84, 85, and 86; and the limitations with respect to mass ratio, for example, recited in claims 96, 98, and 100 are construed to be inherent characteristics of the claimed composition.

Chevalier et al. (US Patent 6,361,782) teach anhydrous compositions prepared according to the method disclosed in the instant application for the skin, including the following (col. 14, lines 26-39; see also instant specification, para 0275):

 a) a liquid fatty phase including polymer particles that are dispersed and surfacestabilized therein; and

10/785,093 Art Unit: 1614

b) a dyestuff,

wherein the liquid fatty phase includes a volatile liquid phase and a non-volatile liquid phase; the non-volatile phase having a solubility parameter < 5 (J/cm3)/2 and wherein a volatile phase/non-volatile phase weight ratio ranges from 2 to 25 (col. 2, lines 25-51). The solubility parameters recited in claims 89-92 overlap with the teaching of Chevalier et al. Chevalier et al. exemplify a polymer dispersion of polymethyl methacrylate crosslinked with ethylene glycol dimethacrylate, in isododecane, prepared in accordance with the method of Example 2 of document EP-A-749 746 (see col. 14. lines 26-39) i.e. a dispersion of surface-stabilized polymethyl methacrylate particles in isododecane with a styrene/copoly (ethylene-propylene) diblock copolymer sold under the name Kraton G1701 (Shell), with a solids content of 19/7% by weight and an average particle size of 135 nm (polydispersity: 0.05) and a Tg of 100 degrees Centigrade. Applicant's exemplified polymer dispersion is comprised of the identical block polystytrene/copoly(ethylene-propylene) diblock copolymer sold under the trade name Kraton G1701. Chevalier et al. et al. compositions comprising non-volatile primary oils, including n-butyl acetate, dibutyl phthalate, which reasonably satisfy the embodiment "c" recited in claims 78 and 114 (see col. 7, line 51 to col. 8, line 61; see also reference claim 8) as evidenced by the teaching of Uchiyama et al. (US Patent Application Pub. No. 20030224030 A1) of plasticizers, including said non-volatile oils disclosed by Chevalier et al. The above teaching of Chevalier et al overlaps with the instant claimed composition comprising a stabilized polymer particle dispersed in a

10/785,093 Art Unit: 1614

liquid fatty phase (col. 14, lines 26-39). Thus, for these reasons claims 89-92 are found to be anticipated by the prior art.

Uchiyama et al. (US Patent Application Pub. No. 20030224030 A1) is only being relied upon as an evidenciary reference.

Claim rejections - 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 78-102, 105, and 114 are rejected under 103(a) as being unpatentable over Chevalier et al. (US Patent 6,361,782) and Ferrari et al. (US Patent Application Pub. No. 2002/0164297 A1), in view of Uchiyama et al. (US Patent Application Pub. No. 20030224030 A1).

10/785,093 Art Unit: 1614

The above discussions of Ferrari et al. and Chevalier et al. in connection with the rejections under 102(a) are incorporated by reference.

The limitations with respect to solubility parameters, for example, recited in claims 89 and 91; the limitations with respect to molecular mass, for example, recited in claims 83, 84, 85, and 86; and the limitations with respect to mass ratio, for example, recited in claims 96, 98, and 100 are construed to be coextensive characteristics of the claimed composition.

Ferrari et al. and Chevalier et al. do not teach the plasticizers recited in instant claim 101.

Uchiyama et al. (US Patent Application Pub. No. 20030224030 A1) is added to show the general state of the art regarding plasticizers (para 0041). Uchiyama et al. teach non-limiting examples of suitable plasticizers, including acetyl tributyl citrate, acetyl triethyl citrate, acetyl triethyl citrate, acetyl trihexyl citrate, butyl benzyl phthalate, butyloctyl benzoate, butyl phthalyl butyl glycolate, butyroyl trihexyl citrate, camphor, decyloxazolidinone, dibutyl adipate, dibutyl oxalate, dibutyl phthalate, ..., diethylene glycol, diethylhexanoate/diisononanoate, ..., diethylhexyl adipate, diethyl phthalate, diethyl sebacate, ..., sucrose acetate isobutyrate, sucrose Benzoate ... and mixtures thereof (para 0041).

The above references in combination make clear that plasticizers are included in the compositions taught by each reference. Thus, it is obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose because the idea of combining the above cited references flows logically from their

10/785,093 Art Unit: 1614

having individually been taught in the prior art. The combination of active ingredients with the same character is merely the additive effect of each individual component. See In re Kerkhoven. 205 USPQ 1069 (CCPA 1980).

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

10/785,093 Art Unit: 1614

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

activities undertaken within the scope of a joint research agreement.

Claims 78-102, 105, and 114 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58, and 64 of copending application No. 10/784,949; claims 1-84 of copending application No. 10/529,318; claims 1-43 of copending application 11/147,352; claims 1-57 of copending application 11/147,318; claims 1-42 of copending application 11/147,353; claims 1-58 and 62 of copending application 12/004,050; all in view of Chevalier et al. (US Patent 6,361,782) and Uchiyama et al. (US Patent Application Pub. No. 20030224030 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

The above discussion of Chevalier et al. and Uchiyama et al. in connection with the rejection under 103(a) is incorporated by reference.

These are <u>provisional</u> obviousness-type double patenting rejections because the conflicting claims of the copending applications have not in fact been patented.

10/785,093 Art Unit: 1614 Page 14

Relevant Art of Record

The below cited art made of record and relied upon are considered pertinent to applicant's invention.

Application/Control Number: 10/785.093

Art Unit: 1614

Arnaud et al. (US Patent 6.326.012) teach anhydrous cosmetic compositions comprising, in a physiologically acceptable medium, a combination of a volatile hydrocarbon-based oil and a functionalized synthetic wax, wherein said combination provide transfer resistance properties to make-up or care compositions for the skin, keratin fibers or the lips, wherein the hydrocarbon-based waxes are of a particular class characterized by a specific melting point range and specific solubility parameters that solve the recognized problem in the art regarding the addition of hardening compounds to solid formulation (col. 1, lines 8-52; see also reference claims 1, 14, and 15). Arnaud et al. (US Patent 6,326,012) exemplify lipsticks formulations comprising applicant's elected Performacol 550 linear fatty in an amount of 10% (see instant specification. pages 55-56, including Examples 1 and 1). Arnaud et al. exemplified lipstick formulations also comprise Performalene 500 polyethylene wax (New Phase Technologies) in an amount of 10-23 wt %, isododecane in an amount of 33.61-40 wt %, cyclopentapolysiloxane in an amount of 8,39-10 wt %, polyisobutene in an amount of 2.9 wt %, titanium oxide in an amount of 3.3 wt %, DC Red No. 7 calcium lake in an amount of 1.80 wt %, aluminum lake in an amount of 0.06 wt %, DC Red No. 21 aluminum lake in an amount of 0.6 wt % (see col. 8, Example 3). Applicant's Example 2 lipstick formulation also comprise polyethylene wax (weight-average molecular mass: 500: see instant specification page 55).

Lorensen et al. (US Patent 3,238,133) teach that polymeric esters of alkanols having at least 30 carbon atoms or copolymers of such C30-C50 alkyl methacrylates in which the former is in predominant amounts possess detergent and dispersant

10/785,093 Art Unit: 1614

properties (col. 1, line 56 to col. 2, line 2). Lorensen et al. teach lubricating oils derived from coal products, and synthetic oils, e.g. ethyl alcohol, dicarboxyliv acid esters (e.g. those which are prepared by esterifying such dicarboxylic acids as adipic acid, azelaic acid, suberic acid, sebacic acid, succinic acid, fumaric acid, maleic acid, pimelic acid, etc. with alcohols, such as butyl alcohol, hexyl alcohol, 2-ethylhexyl alchol, dodecyl alcohol. etc.) ... See col. 4, lines 23-41 .. These oils may be used individually or in combination (col. 4, lines 23-41).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like

10/785,093 Art Unit: 1614 Page 17

assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-

1000.

2 July 2008

/Kevin E. Weddington/ Primary Examiner, Art Unit 1614

/C. R./ Examiner, Art Unit 1611